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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,952	03/22/2004	Celso J. Bagaoisan	ACI-003	2852

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EXAMINER

YABUT, DIANE D

ART UNIT PAPER NUMBER

3734

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s) ^{NT}	
	10/806,952	BAGAOISAN ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/7/05; 12/2/05; 1/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-10), Species 3 (Figures 12A-14B) of the sealing apparatus and Species 1 (Figures 18A-19C) in the reply filed on 9 November 2006 is acknowledged.

Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 9 November 2006.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 7 January 2005, 2 December 2005, and 23 January 2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Epstein** (U.S. Patent No. **6,045,570**) in view of **Cates** (U.S. Patent No. **6,162,240**).

Claim 1: Epstein discloses a tubular member **22** having a proximal end, a distal end sized for insertion into a puncture, and a lumen extending between the proximal and distal ends, an elongate occlusion member **33** slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member, an expandable member **34** on the occlusion member distal end, a delivery device **81** coupled to the proximal end of the tubular member, the delivery device comprising a plunger **86** that is advanceable to deliver a sealing compound into the tubular member lumen, and a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member

(Figure 1). Epstein discloses the claimed invention except for the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of the plunger to thereby disengage the lock, the retraction assembly being biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged.

Cates teaches a retraction assembly comprising a lock for securing the tubular member **36** (a housing assembly **35** mounts an introducer assembly, or the tubular member) in a distal position relative to the occlusion member, and a trigger ("retraction mechanism") **38** that is activated by advancement of the plunger **55** to thereby disengage the lock, the retraction assembly being biased to retract the tubular member

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proximally relative to the occlusion member when the lock is disengaged (Figures 1, 7-9 and col. 6, lines 46-60 and col. 7, lines 1-46). Cates teaches that the retraction mechanism allows for selective retraction of the tubular member while protecting the occlusion member prior to deployment and maintaining the occlusion member at a fixed position relative to the blood vessel wall, or tissue puncture. It would have been obvious to one of ordinary skill in the art to provide a retraction mechanism, as taught by Cates, to Epstein in order to selectively retract the tubular member after protecting and positioning the occlusion member prior to deployment, and therefore providing better user control.

Claim 2: Epstein discloses the claimed device except for an outer member comprising proximal and distal ends defining a longitudinal axis therebetween with an inflation lumen extending between the outer member proximal and distal ends, the expandable member comprising proximal and distal ends and having a variable length dimension, the proximal end of the expandable member being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior, and an inner member slidably coupled to the outer member and comprising proximal and distal ends, the inner member distal end coupled to the expandable member distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the proximal end of the expandable member when the expandable member is expanded and collapsed, respectively.

Cates teaches an outer member **36** comprising proximal and distal ends defining a longitudinal axis therebetween with an inflation lumen **28** extending between the outer member proximal and distal ends, the expandable member comprising proximal and distal ends and having a variable length dimension, the proximal end of the expandable member being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior, and an inner member **20** slidably coupled to the outer member and comprising proximal and distal ends, the inner member distal end coupled to the expandable member distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the proximal end of the expandable member when the expandable member is expanded and collapsed, respectively in order to manually manipulate the expandable member and maintain the seal over the puncture (Figures 3 and 6 and col. 6, lines 1-17). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the outer and inner members, as taught by Cates, to Epstein in order to manually manipulate the expandable member and maintain the seal over the puncture.

Claims 3-4: Epstein discloses the claimed device except for a housing on the proximal end of the outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir filled with inflation media and in fluid communication with the chamber, and an actuator that may be activated by a user to

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direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands, and the actuator may be deactivated to withdraw inflation media from the chamber and the inflation lumen into the reservoir, thereby substantially simultaneously collapsing the expandable member and directing the piston distally to push the inner member distally to lengthen the expandable member as it collapses.

Cates teaches a housing ("syringe") 26 on the proximal end of the outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir filled with inflation media and in fluid communication with the chamber, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands and the actuator may be deactivated to withdraw inflation media from the chamber and the inflation lumen into the reservoir, thereby substantially simultaneously collapsing the expandable member and directing the piston distally to push the inner member distally to lengthen the expandable member as it collapses (Figure 1 and col. 6, lines 18-27). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a housing with a chamber in fluid communication with the inflation lumen, a piston slidably

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disposed within the chamber and coupled to the inner member, a reservoir, and an actuator, as taught by Cates, to Epstein since it was known in the art that expandable members are inflated by any convenient fluid inflation device such as a syringe which can be removed from the sealing device.

Claim 5: Epstein discloses the claimed device except for the proximal and distal ends of the expandable member at least partially evert into the interior of the expandable member as the expandable member expands.

Cates teaches the proximal end of the expandable member at least partially evert into the interior of the expandable member as the expandable member expands (Figure 10). Although the distal end of the expandable member does not at least partially evert into the interior of the expandable member as the expandable member expands in Cates, it would have been obvious to one of ordinary skill in the art to have either end or both proximal and distal ends of the expandable member evert into the expandable member, depending on its coupling to the tubular member, and modify Epstein since it was known in the art that the ends everting maintains a seal against fluid escaping as well as the bond around the member onto which it is disposed.

Claim 6: Epstein discloses the claimed device except for the retraction assembly further comprising an elongate member extending distally along a proximal portion of the occlusion member, the elongate member comprising one or more connectors on a distal end thereof, the one or more connectors connectable to the proximal end of the tubular member to thereby couple the tubular member to the retraction assembly.

Cates teaches a retraction assembly **38** further comprising an elongate member **36** extending distally along a proximal portion of the occlusion member, the elongate member comprising one or more connectors **60** on a distal end thereof, the one or more connectors connectable to the proximal end of the tubular member to thereby couple the tubular member to the retraction assembly (Figure 2 and col. 7, lines 29-46). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate member comprising one or more connectors, as taught by Cates, to Epstein since it was known in the art that retraction mechanisms must be coupled to the member that is being retracted by connectors in order for the mechanism to be functional.

Claim 7: Epstein discloses the occlusion member being coupled to the retraction assembly, the elongate member further comprising a sheath **41** extending over the proximal portion of the occlusion member, wherein the sheath may be received in the tubular member lumen when the occlusion member is inserted therein, and one or more connectors being insertable at least partially into the proximal end of the tubular member to couple the tubular member to the sheath (Figure 1 and col. 6, lines 24-26).

4. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein (U.S. Patent No. **6,045,570**) and Cates (U.S. Patent No. **6,162,240**), as applied to Claim 7 above, and further in view of Edwards (U.S. Patent No. **6,562,059**).

Claim 8: Epstein and Cates disclose the claimed device, including tubular member further comprising a housing **46** on the proximal end thereof, the housing defining a

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cavity (Figure 1, Epstein), except for one or more connectors comprising a detent that collapses to allow the detent to be inserted into the cavity when the sheath is received in the tubular member lumen, the detent being biased to extend within the cavity and prevent the detent from being removed easily therefrom.

Edwards teaches one or more connectors comprising a detent that collapses to allow the detent to be inserted into the cavity when the sheath is received in the tubular member lumen, the detent being biased to extend within the cavity and prevent the detent from being removed easily therefrom (col. 7, lines 22-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide one or more connectors comprising a detent, as taught by Edwards, to Epstein and Cates since it was known in the art that biased mechanisms prevent undesirable movement of the sheath relative to the tubular member although still movable when manipulated by the user.

Claims 9-10: Epstein discloses the claimed device including the housing comprising one or more side ports communicating with the delivery device (Figure 1), except for the sheath comprising a lumen and an opening communicating with the lumen that is disposed within the cavity when the detent is inserted into the cavity, the sheath comprising a seal distal to the opening for engaging an inner surface of the tubular member to substantially seal the lumen of the tubular member, such that sealing compound delivered from the delivery device enters the one or more side ports and flows into the opening and through the lumen of the sheath.

Edwards teaches the sheath 52 comprising a lumen and an opening communicating with the lumen that is disposed within the cavity when the detent is inserted into the cavity, the sheath comprising a seal distal to the opening for engaging an inner surface of the tubular member 10 to substantially seal the lumen of the tubular member, such that sealing compound delivered from the delivery device enters the one or more side ports and flows into the opening and through the lumen of the sheath and a distal tip of the sheath extending beyond the distal end of the tubular member when the detent is inserted into the cavity, such that the sealing compound is delivered through the lumen of the sheath out the distal tip of the sheath and beyond the distal end of the tubular member (Figures 4C-4E and col. 6, lines 48-67 and col. 7, lines 1-14 and lines 22-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sheath comprising a lumen and an opening and a seal, as taught by Edwards, to Epstein and Cates since it was known in the art that sealing the lumen while delivering the sealing compound would prevent undesirable leakage or flow within the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER